REMARKS

Claims 1-11 are pending in this application.

Applicants note that this Response is being filed concurrently with, and as part of, a Petition to Revive the present application and as the submission required for the accompanying Request for Continued Examination (RCE).

The October 27, 2004 Advisory Action maintains the rejection of record and again relies on Endikrat et al. in combination with other references to sustain an obviousness rejection under 35 U.S.C. § 103. Applicants reiterate their previously presented comments and respectfully request reconsideration in light of the further comments herein.

Applicants respectfully assert that the Action's reliance on Endikrat et al. is misplaced. Endikrat et al. shows reduced spotting and breakthrough with steroid doses of 30 μg EE when compared to 20 μg EE doses. Endikrat et al. also indicates there are benefits to using low dose, 20 μg EE dose contraceptives. We, however, cannot agree with the Action that there is any teaching, suggestion, or motivation to administer relatively high dose (e.g. 30 μg EE) compositions during the initial cycles followed by relatively low dose (e.g. 20 μg EE) compositions in subsequent cycles or to package the oral contraceptives in cycle kits to facilitate such administration. Endikrat et al., as discussed in Applicant's previous response, simply does not teach or suggest such a treatment regime. In fact, the intent of Endikrat et al. was merely to determine whether a low dose regime could entirely replace the high dose regime without sacrificing contraceptive effectiveness, cycle control, or tolerability. These properties were

substantially similar in both treatment regimes. Thus, Endikrat et al. ultimately concluded "Prescription of 20 μg EE2 preparation could be the first-line therapy in order to provide the lowest amount of EE2 possible. In case of persistent cycle control problems, a switch to the 30 μg EE2 drug should be considered." (see abstract). Thus, Endikrat et al. clearly establishes the protocol, involving a preferred treatment regime of just 20 μg EE2 steroid content from cycle to cycle throughout the treatment period. Even when the content changes, due to control problems, the change is from low content to high content, the exact opposite of the treatment regime facilitated by Applicants' claimed contraceptive kit. Thus, Endikrat et al. teaches away from treatment regimes and kits that facilitate early cycle administration of relatively high doses of steroid followed by subsequent relatively low dose cycle administration. Teaching away is strong evidence of non-obviousness. Accordingly, the obviousness rejection should be withdrawn.

Applicants respectfully request withdrawal of the obviousness rejection under 35 U.S.C. § 103.

Early reconsideration and allowance of all pending claims is respectfully requested. The examiner is requested to contact the undersigned attorney if an interview, telephonic or personal, would facilitate allowance of the claims.

The Commissioner is hereby authorized to charge any required fee to Deposit Account No. 50-1275 for this Response or the associated Renewed Petition For Revival. This authorization can also be found on the Fee Transmittal filed herewith.

Respectfully submitted,

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Date: December 23, 2004

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